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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 09/844,281 | 04/30/2001 | Beverly Lynn Mangold | 38602.0003 | 1022 |
| 20350 | 7590 | 10/03/2006 | EXAMINER | |
| TOWNSEND AND TOWNSEND AND CREW, LLP TWO EMBARCADERO CENTER EIGHTH FLOOR SAN FRANCISCO, CA 94111-3834 | | | GRASER, JENNIFER E | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1645 | |

DATE MAILED: 10/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/844,281

Applicant(s)

MANGOLD ET AL.

Examiner

Jennifer E. Graser

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 7/20/06.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16-19, 44, 50-54 and 56-85 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16-19, 44, 50-54 and 56-85 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/20/06</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

1. Acknowledgment and entry of the Amendment submitted on 7/20/06 is made.

Claims 16-19, 44, 50-54, and 56-85 are currently pending.

Claim Rejections - 35 USC § 112

2. Claims 16-19, 44, 50-54, and 56-85 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 16, 19, 59, 66, 69 and 79 are vague and indefinite due to the phrase “specifically binds spores or vegetative cells of *B.anthraxis relative to* the spores or vegetative cells of *B.thuringiensis*, etc...”. The term “relative to” is defined as “with regard to; concerning, e.g., questions relative to the deficit. Having pertinence or relevance; connected or related.

<http://www.answers.com/topic/relative> American Heritage Dictionary. Defines relative as:

1. Considered in comparison with something else: *the relative quiet of the suburbs*
2. Having pertinence or relevance; connected or related.

Accordingly, it is unclear what is intended by this language. This language does not convey that the isolated antibody or fragment only binds *B.anthraxis* and not the other spores or vegetative cells.

With respect to claims 16, 19, 59, 66, 69 and 79 the amino acid sequence of EA1, e.g., SEQ ID NO:1 or the deposited antibody, should be inserted in the claims. The mere recitation of a name, i.e., EA1, to describe the invention is not sufficient to satisfy the Statute's requirement of adequately describing and setting forth the inventive concept. The claim should provide any structural properties, such as the amino acid sequence of the protein or molecular weight, which would allow for one to identify the protein without ambiguity. The mere recitation of a name does not adequately define the claimed antibody. The antigen to which the antibody binds is a critical limitation. While the specification can be used to provide definitive support, the claims are not read in a vacuum. Rather, the claim must be definite and complete in and of itself. Limitations from the specification will not be read into the claims. The claims as they stand are incomplete and fail to provide adequate structural properties to allow for one to identify what is being claimed.

Response to Applicants Arguments. Applicants argue that the skilled person would be apprised of relevant background information regarding EA1 polypeptide, or protein, from B.anthraxis. They cite prior art references on page 12 of the response. It is stated that each of these references recite that EA1 antigen is recognized as a distinct entity in comparison to other components or parts of B.anthraxis. They argue that the references describe that the polyclonal antibodies which bind to EA1 are cross-reactive with both B.thuringiensis and B.cereus. They argue the references teach the amino acids sequence of the EA1 antigen and its purification and characterization.

These arguments have been fully and carefully considered but are not deemed persuasive. Applicants have stated that they have discovered epitopes of the EA1 antigen which can be used to generate antibodies which can specifically identify B.anthraxis apart from other Bacillus organisms, such as B.cereus or B.thuringiensis. The rejection remains because the claims fail to teach these specific epitopes or claim the structure of these antibodies which bind them. A deposit of these antibodies would cure this deficiency.

Claim 64 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: there is no correlation step, e.g., what does detecting the complex tell one? Additionally, what type of sample is used?

Claim Objections

3. Claim 68 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 18. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

It appears the dependency in claim 68 should be to claim 66, not claim 16.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 16-19, 44, 50-54, and 56-85 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for “monoclonal antibody AX-EA1-G1 which was deposited with the ATCC and accorded accession number PTA-2632, on October 26, 2000 and shown to have strong reactivity against B. anthracis antigens and negative reactivity against the closely related strains of B.thuringiensis (ATCC 33680, HD571, A1 Hakam, and commercial insecticide preparation from Dipel Dust), B. globigii and B. licheniformis (ATCC 25972) (Table 2, 3 and 4)”. [The specification also recites that three monoclonal antibodies (termed AX-EA1- G1, 8G4, and 9F5) were selected for their ability to uniquely detect B. anthracis and not cross-react with other closely related Bacillus species; however it does not appear that deposit was made of these 3 antibodies and therefore, until Deposit requirements are met, the specification is only enabled for the monoclonal antibody designated as PT-2632], does not reasonably provide enablement for the broad scope of the claims which include antibodies outside of the deposited antibody. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Applicants have stated on page 11 of the response dated July 20, 2006 that the invention is based on the discovery that there are epitopes of the EA1 polypeptide that may be used to specifically identify B.anthraxis apart from other organisms such as, B.cereus or B.thuringiensis. They state that the discovery was based upon antibodies that bind epitopes found on B.anthraxis and not on other Bacillus species and they cite paragraphs 0036 to 0039 and Tables 1-4 as examples. They state that since the

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antibodies were found on the EA1 polypeptide of *B.anthraxis*, they were described as binding the EA1 polypeptide. They do note that the antibodies may bind other *Bacillus* organisms such as to the OlpA polypeptide of *B.licheniformis*.

The instant claims are drawn to the discovered invention, but encompass antibodies which have not been discovered. The novel epitopes or the antibodies are not structurally recited in the claims. The functional limitations are not enough to allow one to identify the structure which is being claimed. The scope of the claimed invention is much broader than what is taught in the instant specification. *Genentech Inc. v. Novo Nordisk A/S* (CAFC) 42 USPQ2d 1001 clearly states: "Patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable. See *Brenner v. Manson*, 383 U.S. 519, 536, 148 USPQ 689, 696 (1966) (stating, in context of the utility requirement, that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.") Tossing out the mere germ of an idea does not constitute enabling disclosure. While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention." The claims should be amended so that the antibodies are claimed by deposit information. The claims could also be amended to recite the specific epitope, by SEQ ID NO. to which the antibodies bind, provided there is support in the instant specification. It appears that the top of page 14 of the instant specification recites that, it can be concluded that the epitope to which AX-EA1-G1 binds is located somewhere

within amino acids 181-833. However, it does not appear that this information would be sufficient to enable anything broader than the deposited antibodies.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claim 16, 44, 50-54, and 56-65 are rejected under 35 U.S.C. 102(b) as being anticipated by Mesnage et al (Molec. Microbiol. 1997, 2346): 1 147-1 155).

Mesnage et al teach isolated antibodies to the Bacillus anthracis S-layer component, **EAI**. The major cell antigen to which the isolated antibodies bind in the Mesnage reference is 100% identical to the EAI protein disclosed by Applicants and set forth in SEQ ID NO: 1. It is taught that a Western blot assay suggested that the antibodies were highly specific to B.anthraxis and did not cross-react. See page 1150-1151. Electron microscopy using grids with rabbit anti-EAI antibodies or rabbit anti-sap antibodies, or on anti-sap antibodies. The grids were incubated on colloidal gold anti-rabbit or anti-mouse coupled antibodies. The Western blots and grids performed with the EA1 antibodies anticipate the method of claim 64 as they include contacting an antibody/fragment with a sample, forming a complex and detecting said complex.

Applicants have disclosed in the instant specification that antibodies directed against this EAI protein are antibodies which bind to B.anthraxis, but do not bind to B.thuringiensis. These antibodies are disclosed as the preferred embodiment in the

instant specification. Although the reference does not specifically recite that the antibody to *B.anthraxis* does not specifically react with *B.thuringiensis*, it inherently would not since the antigen to which it binds is specific to *B.anthraxis* and the instant specification supports this finding. The antibodies to the EAI protein would be identical to Applicant's antibodies to the EAI antibody, i.e., the antibodies are raised against the same antigen. There are no structural differences between the prior art antibody, e.g., specifically binds EA1 antigen of *B.anthraxis*, and those that are instantly claimed. The intended use of the claimed composition does not patentably distinguish the composition, *per se*, since such undisclosed use is inherent in the reference composition; e.g., does not bind *B.thuringiensis* or *B.cereus*. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. An antibody produced from the hybridoma deposited as PTA-2632 would also possess the same binding capabilities of the claimed fragments and antibodies.

Since the Patent Office does not have the facilities for examining and comparing Applicant's antibody with the antibody of the prior art, the burden of proof is upon applicants to show an unobvious distinction between the material structural and functional characteristics of the claimed antibody and the antibody of the prior art. See *In re Best*, 195 USPQ 430, 433 (CCPA 19&&). Since the instant kit claims do not

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require any components other than the antibodies, the reference anticipates the claims. The phrase "diagnostic kit" is an intended use only. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Response to Applicants' Arguments:

The instant specification only recites that the claimed antibody binds to an epitope somewhere amino acids 181-833. The EA1 protein is 833 amino acids in length. It appears that Mesnage's antibody binds somewhere within those amino acids as well, absent specific structural evidence to the contrary.

Applicants argue that Mesnage teach the production of rabbit polyclonal antibodies in sera against EA1 polypeptide and that there is no indication that this antiserum was specific for B.anthraxis. This has been fully and carefully considered but is not deemed persuasive. The scope of the instant claims includes polyclonal antibodies, particularly polyclonal antibodies generated from any source. Polyclonal antibodies specifically raised against a defined antigen, e.g., EA1, would 'specifically bind' that antigen. It is irrelevant that Mesnage do not provide cross-reaction studies against B.thuringienensis or B.cereus, the antibodies are structurally the same to that which is claimed and, therefore, would inherently possess the same binding capabilities. Applicants argue that the intended use of their antibodies 'does not bind B.thuringiensis or B.cereus' is enough to distinguish over the prior art of record. This is not deemed

persuasive. There are no structural differences between the prior art antibody, e.g., specifically binds EA1 antigen of *B.anthraxis*, and those that are instantly claimed. The intended use of the claimed composition does not patentably distinguish the composition, *per se*, since such undisclosed use is inherent in the reference composition; e.g., does not bind *B.thuringiensis* or *B.cereus*. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting. There is nothing in the claims which distinguishes the structure of the antibody with the antibodies taught by Mesnage. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. An antibody produced from the hybridoma deposited as PTA-2632 would also possess the same binding capabilities of the claimed fragments and antibodies.

Additionally, Mesnage specifically teach that a Western blot assay suggested that the antibodies (to EA1) were highly specific to *B.anthraxis* and did not cross-react. See page 1150-1151.

Since the Patent Office does not have the facilities for examining and comparing Applicant's antibody with the antibody of the prior art, the burden of proof is upon applicants to show an unobvious distinction between the material structural and functional characteristics of the claimed antibody and the antibody of the prior art. See *In re Best*, 195 USPQ 430, 433 (CCPA 19&&).

Applicants arguments about Mesnage not modifying his antibodies to be specific for B.anthraxis are moot since the antibodies taught by Mesnage are structurally identical to the antibodies recited in the instant claims. Accordingly, they would possess identical properties.

It is especially noted that the instant claims allow for fragments of antibodies as well and do not require the antibody to bind to any specific epitope along the EA1 polypeptide. The language of the instant claims allow for the antibody to bind to any epitope or epitopes of the EA1 antigen. The antibody taught by Mesnage binds to an antigen which is 100% identical to the antigen to which Applicants' antibody binds. Accordingly, since the antibodies claimed are structurally the same, e.g, bind EA1 antigen, they would inherently possess the same cross-reactive properties.

Since the Patent Office does not have the facilities for examining and comparing Applicant's antibody with the antibody of the prior art, the burden of proof is upon applicants to show an unobvious distinction between the material structural and functional characteristics of the claimed antibody and the antibody of the prior art. See *In re Best*, 195 USPQ 430, 433 (CCPA 19&&).

Claim Rejections - 35 USC § 103

8. Claims 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mesnage et al (Molec. Microbiol. 1997, 23(6): 1147-1 155), as applied to claims 16, 44, 50-54, and 56-63 above, in view of Loomis et al (WO 99/64863).

Mesnage et al teach antibodies to the Bacillus anthracis S-layer component, EAI. It is disclosed that EAI constitutes the main lattice of the B.anthraxis S-layer, and is the

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major cell-associated antigen. See abstract. Antibodies to the surface array protein (Sap) are also taught. It is taught that a Western blot assay suggested that the antibodies were highly specific to B.anthraxis and did not cross-react. See page 1150-1151. Electron microscopy using grids with rabbit anti-EAI antibodies or rabbit anti-sap antibodies, or on anti-sap antibodies. The grids were incubated on colloidal gold anti-rabbit or anti-mouse coupled antibodies. The major cell antigen to which the isolated antibodies bind in the Mesnage reference is 100% identical to the EAI protein disclosed by Applicants. Applicants have disclosed in the instant specification that antibodies directed against this EAI protein are antibodies which bind to B.anthraxis, but do not bind to B.thuringiensis. These antibodies are disclosed as the preferred embodiment in the instant specification. However, Mesnage et al does not particularly exemplify the use of these antibodies in a colloidal particle based lateral flow detection system.

Loomis et al teach that colloidal gold particle immunoassays have been successfully used in the prior art for many years. See pages 1-3. Loomis et al teach a more sensitive immunoassay test to what was known in the art. It is a colloidal colorimetric flow through and lateral flow assay. The entire test is conducted on a test strip and the detection antibody is preferably a FAB fragment that has been labeled with a 50-100nm gold particle and immobilized on a test pad. See page 4. It is taught that the use of capture dendrimers to align and secure capture antibodies on a solid surface insure that no immunological activity of the capture antibody is sterically hindered.

It would have been prima facie obvious to one of ordinary skill in the art to use the antibodies taught by Mesnage et al in a colloidal lateral flow detection system as taught by Loomis et al to detect B.anthraxis because Mesnage et al teach that the antibodies are highly specific to B.anthraxis and that EAI constitutes the main lattice of the B.anthraxis S-layer, and is the major cell-associated antigen. One of ordinary skill in the art would have a reasonable expectation that a specific antibody developed against the major cell-associated antigen of a bacterium to be very effective in detecting the bacterium in a sample. Loomis et al teaches that it is a highly sensitive detection assay which is simple, sensitive and specific. The use of the EAI and/or Sap antibodies taught by Mesnage in a colloidal lateral flow detection system would have been obvious as a B.anthraxis detection system. The assembly of the reagents to these assays in a diagnostic kit would have been obvious to one of ordinary skill in the art at the time the invention was made for convenience and storage capabilities.

Response to Applicants' Arguments:

Applicants' arguments are directed to the Mesnage reference. These arguments were addressed in the 'Response to Applicants' Arguments' section under the 102 Mesnage rejection above.

9. Claim 55 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mesnage et al (Molec. Microbiol. 1997, 23(6): 1147-1 155), as applied to claims 16, 44, 50-54, and 56-63 above, in view of Kohler et al (Science. 1986. 233: 1281-1285)

The teachings of Mesnage are set forth above. However, they do not specifically teach monoclonal antibodies to the EA1 antigen.

Kohler et al teach that making monoclonal antibodies to known antigens was common and have greater specificity than polyclonal antibodies and can be readily produced in great quantities.

It would have been obvious to one of ordinary skill in the art at the time the invention was made that monoclonal antibodies to the EA1 antigen could be generated/used in place of polyclonal antisera because it was well known in the prior art as evidenced by Kohler that, in general, monoclonal antibodies have proven superior to polyclonal antisera both in terms of production and clinical utility. Polyclonal antisera are not only costly and labor intensive to produce, but they are also difficult to quality control because each immunized rabbit can produce only so much antisera and every new rabbit is different. Therapeutically, monoclonals can more precisely impact a target, often with fewer adverse effects and greater specificity. Accordingly, one of ordinary skill in the art would have been motivated to make monoclonal antibodies to the EA1 antigen.

10. Claim 16, 18, 44, 50-54, and 56-66, 68, 79-85 are rejected under 35 U.S.C. 102(b) as being anticipated by Ezzell et al. (Infection and Immunity. Feb. 1988. 56(2): 349-356).

Ezzell et al teach isolated antibodies to, **EAI**. The major cell antigen to which the isolated antibodies bind in the Ezzell reference is 100% identical to the EAI protein disclosed by Applicants and set forth in SEQ ID NO: 1. Quantitation of antibody titers to EA1 in sera from guinea pigs was accomplished through ELISA (see page 351, column 1). The assays performed with the EA1 antibodies anticipate the method of claim 64 as

they include contacting an antibody/fragment with a sample, forming a complex and detecting said complex. Indirect immunofluorescence assays are also taught. Vaccine trials were performed with EA1 and antibodies to EA1 were measured. Mouse monoclonal antibodies to EA1 are also taught. See page 355, column 1, halfway down the page.

Applicants have disclosed in the instant specification that antibodies directed against this EAI protein are antibodies which bind to *B.anthraxis*, but do not bind to *B.thuringiensis*. These antibodies are disclosed as the preferred embodiment in the instant specification. Although the reference does not specifically recite that the antibody to *B.anthraxis* does not specifically react with *B.thuringiensis*, it inherently would not since the antigen to which it binds is specific to *B.anthraxis* and the instant specification supports this finding. The antibodies to the EAI protein would be identical to Applicant's antibodies to the EAI antibody, i.e., the antibodies are raised against the same antigen. There are no structural differences between the prior art antibody, e.g., specifically binds EA1 antigen of *B.anthraxis*, and those that are instantly claimed. The intended use of the claimed composition does not patentably distinguish the composition, *per se*, since such undisclosed use is inherent in the reference composition; e.g., does not bind *B.thuringiensis* or *B.cereus*. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed

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invention and the prior art in order to patentably distinguish the claimed invention from the prior art. An antibody produced from the hybridoma deposited as PTA-2632 would also possess the same binding capabilities of the claimed fragments and antibodies.

Since the Patent Office does not have the facilities for examining and comparing Applicant's antibody with the antibody of the prior art, the burden of proof is upon applicants to show an unobvious distinction between the material structural and functional characteristics of the claimed antibody and the antibody of the prior art. See *In re Best*, 195 USPQ 430, 433 (CCPA 19&&). Since the instant kit claims do not require any components other than the antibodies, the reference anticipates the claims. The phrase "diagnostic kit" is an intended use only. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Status of Claims:

No claims are allowed. Applicants have been arguing distinct and unexpected antibodies, yet those antibodies are not claimed. The antibodies instantly claimed do not structurally differ from those taught in the prior art. If Applicants can demonstrate that an antibody generated from their hybridoma is structurally different from that known in the prior art, then the antibody made from the hybridoma should be claimed- along with specific evidences filed to demonstrate it is unique from that of the prior art. The specification appears to indicate, at the top of page 14, that the exact location of the

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epitope which the claimed antibodies bind was not known at the time the invention was made.

It is also noted that antibodies which bind to the OlpA polypeptide of B.anthraxis would also be expected to bind to the EA1 polypeptide of B.anthraxis because of the high homology of the two proteins and the likelihood of identical epitopes.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

11. Correspondence regarding this application should be directed to Group Art Unit 1645. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Remsen. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Group 1645 Fax number is 571-273-8300 which is able to receive transmissions 24 hours/day, 7 days/week.

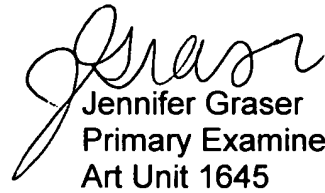
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer E. Graser whose telephone number is (571)

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272-0858. The examiner can normally be reached on Monday-Thursday from 7:30 AM-6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Navarro, can be reached on (571) 272-0861.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-0500.

 9/21/16
Jennifer Graser
Primary Examiner
Art Unit 1645